Section 6: 510(k) SUMMARY

JAN - 7 2011

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Hospira, Incorporated
Address	D-389, Bldg. H2 375 N. Field Drive Lake Forest, IL 60045
Phone number	(224) 212-5316
Fax number	(224) 212-5401
Establishment Registration Number	3005579246
Name of contact person	Karen Keener/Rebecca Andersen
Date prepared	October 26, 2010
Name of device	
Trade or proprietary name	Hospira Infusion Sets
Common or usual name	Fluid Delivery Tubing
Classification name	Infusion Sets
Classification panel	Class II
Regulation	21-CFR Part 880.5725 and 21 CFR Part 880.5440
Product Code(s)	80-FRN and 80-FPA
Legally marketed device(s) to which equivalence is claimed	K052052 Hospira PlumA+ and A+3 Infusion System 08/24/2005 K982159 Abbott Plum A+Infusion Pump 01/12/1999 K060806 Gemstar Infusion Pump 04/21/2006
Reason for 510(k) submission	The changes addressed in this submission include: 1. A change in the bonding process 2. The conversion of tubing material from DEHP to Non-DEHP PVC. 3. Other changes include evolutionary changes and previously cleared components or accessories made by or for Hospira that are used with or incorporated into Hospira Infusion sets.

Device description	The Hospira infusion sets, previously cleared in K052052 (Hospira Plum A+,A+3) and K060806 (Gemstar infusion sets) are intended for use with dedicated Hospira Infusion Pumps. Hospira infusion sets are disposable devices for single patient use, which incorporate various set configurations and components which may be shared across Hospira set families. These administration set families include primary sets, secondary sets, extension sets, piggyback sets, gravity sets, microbore sets, macrobore sets, and sets which allow concurrent delivery. These sets provide a range of physical characteristics such as priming volume, length, diameter, materials etc.
Intended use of the device	Hospira infusion sets are intended for use in parenteral, enteral and epidural therapies and the administration of fluids, medications, nutritional fluids, blood and blood products. Safety features on these devices aid in prevention of needle-stick injuries. Indications for use may include hospital and other medical settings, ambulatory and home use,

Summary of the technological characteristics of the device compared to the predicate device

Characteristic	New Device	Predicate [Device Name] [510(k) number]
1. The Intended use	Same	Same
2. The functionality	Same	Same
3. Visual characteristics	Same	Same
4. Bonding process	6. Removal of the solvent used in the bonding process.	Solvent
5. Tubing characteristics	7. Addition of yellow striped tubing material to the product lines a. Non-DEHP PVC b. New colorant formulation	1. DEHP 2. Clear or Yellow striped

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE*

Performance Test Summary-New Device

Characteristic	Standard/Test Method	Standard / Test Title	Device Performance
Biocompatibility	ISO 10993-5: 2009	Cytotoxicity	Pass
Biocompatibility	ISO 10993-10: 2002	Sensitization	Pass
Biocompatibility	ISO 10993-10: 2002	Irritation / Intracutaneous	Pass

		Reactivity	
Biocompatibility	ISO 10993-11:2006	Systemic Toxicity (Acute)	Pass
Biocompatibility	ISO 10993-4:2002	Hemocompatibility	Pass
SAL 10^{-6}	ISO 11137-2:2006	Sterility	Pass
Dimensional Conformance and Connection compatibility	ISO 594-2	Conical Fittings with a 6% (Luer) Taper for syringes, needles, and certain other equipment	Pass

Summary Discussion of Bench Performance Data

The Hospira Infusion sets with laser welded access device passed all specified test requirements. Hospira Infusion sets with Non-DEHP PVC yellow striped tubing, passed all specified test requirements.

The validation and verification testing confirmed these devices meet user needs and design inputs for an Infusion set.

Testing also confirmed physical attributes and device performance meet requirements of the standards listed in the 'Performance test summary" above. These standards address sterility, biocompatibility, particulate, leakage, tensile strength, and filter characteristics.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The Hospira Infusion Sets with the modified bonding process meet the functional claims, and intended use as described in the product labeling. The safety and effectiveness, are substantially equivalent to the predicate Hospira Infusion Sets as cleared in K052052 (Hospira Plum A+,A+3) and K060806 (Gemstar infusion sets).

The claim for substantial equivalence is supported by the information provided in this Special 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Karen Keener
Associate Global Regulatory Affairs
Hospira, Incorporated
375 North Field Drive Building 2
Lake Forest, Illinois 60045-5045

JAN - 7 2011

Re: K103224
Trade/Device Name: Hospira I.V Administration Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 26 2010
Received: October 21, 2010

Dear Ms. Keener:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

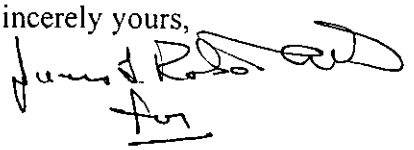
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CONFIDENTIAL

K103224

Indications for use for the subject device Hospira I.V. Administration Sets

Hospira infusion sets are intended for use in parenteral, enteral and epidural therapies and the administration of fluids, medications, nutritional fluids, blood and blood products. Safety features on these devices aid in prevention of needle-stick injuries.

Indications for use may include hospital and other medical settings, ambulatory and home use.

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Prescription Use __X__ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103224